



**State of New Jersey**  
**DEPARTMENT OF HEALTH AND SENIOR SERVICES**  
PO BOX 360  
TRENTON, N.J. 08625-0360

CHRISTINE TODD WHITMAN  
Governor

[www.state.nj.us/health](http://www.state.nj.us/health)

February 16, 2000

Food and Drug Administration  
Center for Biologics Evaluation and Research  
Docket No. 97N-484S  
Dockets Management Branch (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Comments on proposed rules**  
**Part 1271 Federal Register**  
**Vol. 64 #189 9/30/99**

Dear Ms. Zoon:

I have reviewed the proposed rule for "Suitability Determination for Donors of Human Cellular and Tissue Based Products". Comments are as follows:

- The proposed rules do not require that permanent deferral records be maintained.
- The proposed rules do not require that the names of donors identified at the time of screening and testing as unsuitable be saved for listing in deferral records.
- 1271.75(d) – The proposed rules only require an abbreviated donor screening for living donors on subsequent donation when a complete donor procedure has been performed within the previous 6 months. A complete screening should be recorded with each donation event.

If you have any questions, please contact Marilou Mallada at (609) 292-0522 or myself at (609) 984-0488.

Sincerely,

Thomas Domenico, Ph.D.  
Director, Clinical Laboratory  
Improvement Service

97N-484S

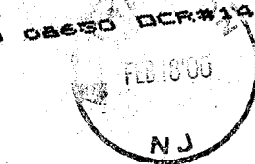


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Many Faces. One Family.

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